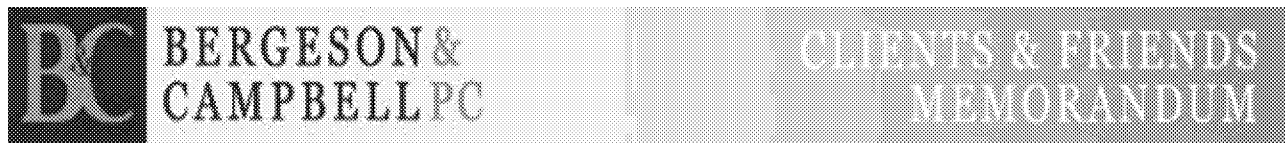


From: Bergeson & Campbell, P.C. [alerts@news.lawbc.com]
Sent: 8/17/2021 1:03:42 AM
To: Krasnic, Toni [krasnic.toni@epa.gov]
Subject: Recent Federal Developments



[Click here to view with images.](#)
To ensure delivery to your inbox please add us to your address book.



Your Global Business Partner for Chemical Law and Science®

Print-friendly PDF

2021 M. 8



PFAS Reporting Rules - What Every Company Needs To Know:
When it comes to per- and polyfluoroalkyl substances (PFAS), the U.S. Environmental Protection Agency (EPA) is not messing around. The Agency announced on June 10, 2021, three actions intended to protect communities from PFAS:

- Proposing a rule designed to obtain comprehensive data on more than 1,000 PFAS manufactured in the United States,
- Withdrawing guidance that EPA believes weakened its July 2020 significant new use rule (SNUR) restricting certain long-chain PFAS, and
- Publishing a final rule that incorporates three additional PFAS into the Toxics Release Inventory (TRI) maintained under the Emergency Planning and Community Right-to-Know Act (EPCRA).

In light of this, Bergeson & Campbell, P.C. (B&C®) is pleased to announce a complimentary webinar focused on these issues on **September 9, 2021, 11:00 a.m. - 12:00 p.m. (EDT)**. B&C Managing Partner Lynn L. Bergeson and Director of Chemistry Richard E. Engler, Ph.D., will discuss EPA's

Not krasnic.toni@epa.gov? If this email was forwarded to you and you would like to subscribe to our mailings please click "Subscribe."

Subscribe To Our
Mailings

In This Update

TSCA/FIFRA/TRI

RCRA/CERCLA/
CWA/CAA/PHMSA/
SDWA

FDA

NANOTECHNOLOGY

BIOBASED/
RENEWABLE
PRODUCTS

proposed rules and what the regulated community must know and do to comply. Register now.

The Critical Role Of Product Stewardship In Business Continuity, August 19, 2021, 1:00 p.m. - 2:00 p.m. (EDT), via webinar: Join the Product Stewardship Society (PSS) and a panel of experts for a unique webinar on how your role as a product steward can make an impact. “The Critical Role of Product Stewardship in Business Continuity” includes a facilitated panel discussion with real-world examples provided of product stewardship management in the aftermath of disruptive events like the pandemic. Specific examples will be shared to illustrate how product stewards can help organizations successfully transition from incident management to recovery and resume operations in a “new normal.” B&C is pleased to sponsor this complimentary webinar.

TSCA/FIFRA/TRI

PFAS Podcast: A thorough discussion of EPA’s proposed PFAS rules is available now on our All Things Chemical™ podcast episode *New PFAS: Is anything NOT reportable? — A Conversation with Richard E. Engler, Ph.D.* A **transcript of the episode** is available to download [here](#).

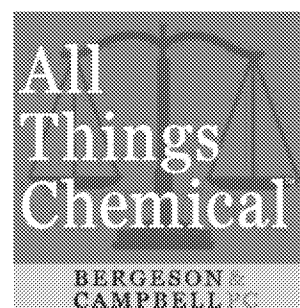
EPA Seeks Comments On Petition Filed To Cancel Seresto Registration: On July 12, 2021, EPA announced in the *Federal Register* a notice of availability of a petition filed on April 8, 2021, by the Center for Biological Diversity (CBD) requesting that EPA cancel Elanco US Inc.’s (formerly Bayer Healthcare LLC) insecticide product PNR1427, more commonly known by its brand name as Seresto (Petition). 86 Fed. Reg. 36546. The Petition also requests that EPA suspend the registration pending the requested cancellation. Seresto has been registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) since 2012 for flea and tick treatment on adult dogs and puppies and on adult cats and kittens. Comments on the Petition are due on or before **September 10, 2021**, in docket EPA-HQ-OPP-2021-0409. More information is available in our July 15, 2021, [blog](#).

EPA Publishes Receipt And Status Information For Certain New Chemicals: On July 21, 2021, EPA published the receipt and status reports for Toxic Substances Control Act (TSCA) Section 5 submissions for June 2021. 86 Fed. Reg. 38475. EPA provides notice of receipt of a premanufacture notice (PMN), significant new use notice (SNUN), or microbial commercial activity notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. EPA also provides information on its [website](#) about cases reviewed under TSCA, including the Section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA’s determination for PMN/SNUN/MCAN notices. Comments identified by the specific case number are due **August 20, 2021**.

EPA Funding For Early Childhood Developmental Health Research Will Include Focus On Chemical Exposures: On July 27, 2021, EPA announced that it will provide \$3.8 million in funding to create two EPA Science to Achieve Results (STAR) Centers for Early Lifestage Vulnerabilities to Environmental Stressors. The centers will focus on early lifestage exposures to chemicals and non-chemical environmental stressors and how these exposures may impact early childhood developmental health. Exposures to cumulative mixtures of chemicals, along with other stressors,

LEGISLATIVE

MISCELLANEOUS



Listen Now!

Occupational Exposure Limits for Nanomaterials — A Conversation with Carla Hutton

An explosive conversation about GHS and combustible dust — with Karin Baron

New PFAS: Is anything NOT reportable? — A Conversation with Richard E. Engler, Ph.D.

such as poverty, limited access to services, and changing environmental conditions, may pose developmental and lifelong health risks. According to EPA, accurate and comprehensive assessments of cumulative impacts are needed to make sound decisions regarding risk reduction, mitigation, and prevention measures.

EPA Will Not Extend August 16, 2021, Comment Period Related To Webinar On Tiered Data Reporting Rule Under TSCA: According to a memorandum posted in Docket ID EPA-HQ-OPPT-2021-0436, EPA will not extend the comment period stemming from the July 27, 2021, public webinar on the development of a proposed rule under TSCA to implement a tiered data collection strategy intended to inform EPA's prioritization, risk evaluation, and risk management activities for chemical substances or mixtures. According to the memorandum posted in the docket, the **August 16, 2021**, deadline is for EPA's use in the current stage of its rulemaking development. While EPA will consider later comments as it continues to develop the proposed rule, EPA states that "comments submitted at this point will be especially useful to EPA and stand a greater chance of influencing the rulemaking." See more information on the July 27, 2021, webinar in our July 29, 2021, memorandum, "EPA Holds Public Webinar on Development of Proposed TSCA Data Reporting Rule." Information on EPA's August 5, 2021, meeting with the Environmental Defense Fund (EDF) to clarify concepts from the webinar is available in our August 16, 2021, blog item.

Preliminary Data For 2020 TRI Reporting Include First-Ever Reporting On PFAS: On July 29, 2021, EPA announced the availability of the preliminary TRI data on chemical releases, chemical waste management, and pollution prevention activities that took place during 2020 at almost 21,000 federal and industrial facilities in the United States. EPA notes that the preliminary data include the first-ever reporting on PFAS added to the TRI by the 2020 National Defense Authorization Act (NDAA). The dataset is raw data and does not contain any summary or trend analysis. EPA plans to publish the updated TRI dataset in **fall 2021**, and EPA will use it to develop the 2020 TRI National Analysis. EPA expects to publish the 2020 TRI National Analysis in **early 2022**. According to EPA, the public can use the preliminary data to identify facilities that report to TRI (for example, to locate facilities in a given ZIP code) and learn which chemicals facilities manage and in what quantities. More information is available in our August 2, 2021, blog item.

EPA Will Delay 1,4-Dioxane Risk Management Until Nearing Completion Of Reconsideration Of Risk Evaluation: In a July 30, 2021, filing in the U.S. Court of Appeals for the Ninth Circuit, EPA states that it cannot "meaningfully commence" risk management rulemaking for 1,4-dioxane until it nears completion of its reconsideration of the final risk evaluation. EPA released the final risk evaluation for 1,4-dioxane on January 8, 2021, in the final weeks of the Trump Administration. On June 30, 2021, the Biden-Harris EPA announced several policy changes regarding risk evaluations issued under TSCA and the path forward for the first ten chemicals to undergo risk evaluation. According to the announcement, EPA intends to re-open and update the 1,4-dioxane risk evaluation to consider whether to include additional exposure pathways and conditions of use that were excluded from the supplemental and final risk evaluations. For more information, please read the full memorandum.

EPA Extends Comment Period On Proposed TSCA Reporting And Recordkeeping Requirements For PFAS: As reported in our June 28, 2021, blog item, EPA proposed reporting and recordkeeping requirements for PFAS under TSCA. 86 Fed. Reg. 33926. On August 3, 2021, EPA extended the comment deadline to **September 27, 2021**. 86 Fed. Reg. 41802. The proposed rule would require certain persons that manufacture (including import) or have manufactured PFAS in any year since January 1, 2011, to

report information electronically regarding PFAS uses, production volumes, disposal, exposures, and hazards. More information is available in our June 11, 2021, memorandum, “EPA Announces Three PFAS Actions, Including Proposed TSCA Section 8(a) Reporting Rule.”

EPA Funds Research To Understand Better Exposure Of Young Children To Chemicals In Soil And Dust: On August 6, 2021, EPA announced that it will provide \$9,272,545 in funding to seven institutions for research to estimate better children’s chemical exposures from soil and dust ingestion. According to EPA, the research will focus on improving estimates of children’s ingestion rates of chemicals such as lead, mercury, polychlorinated biphenyls (PCB), and asbestos. EPA states that “[a]ccurate, comprehensive measurements of soil and dust ingestion rates are critical for effective risk assessment, reduction, mitigation, and prevention measures.”

EPA Adds 36 Chemicals To The Safer Chemical Ingredients List: On August 10, 2021, EPA announced that it added 36 chemicals to the Safer Chemical Ingredients List (SCIL). EPA states that the SCIL “is a living list of chemicals, by functional-use class, that EPA’s Safer Choice program has evaluated and determined meet Safer Choice criteria.” Listed chemicals “are among the safest for their functional use.” In the coming year, EPA hopes to expand the Safer Choice program “to make products containing safer chemicals increasingly available to underserved communities, including communities of color and low-income communities.”

EPA Announces Appointments Of New Members For The FIFRA SAP: On August 13, 2021, EPA announced that it appointed two new members, Cheryl A. Murphy, Ph.D., Professor, Director of Center for PFAS Research, Michigan State University, and Veronica J. Berrocal, Ph.D., Associate Professor, Department of Statistics, University of California, to serve on the FIFRA Scientific Advisory Panel (FIFRA SAP). The Chair and one other existing member also were reappointed. These appointments, effective July 30, 2021, were made by the EPA Administrator following nominations provided by the National Institutes of Health (NIH) and the National Science Foundation (NSF). More information is available in our August 15, 2021, blog.

EPA Issues Final SNURs On Certain Chemical Substances: EPA issued on August 16, 2021, final SNURs under TSCA for chemical substances that were the subject of PMNs. 86 Fed. Reg. 45651. The SNURs require persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use by the SNURs. The SNURs further require that persons not commence manufacture or processing for the significant new use until they have submitted a SNUN, EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken any risk management actions as are required as a result of that determination. The SNURs will take effect on **October 15, 2021**.

RCRA/CERCLA/CWA/CAA/PHMSA/SDWA

EPA Requests Comments On Draft CCL 5: On July 19, 2021, EPA published for comment a draft list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations for public review and comment. 86 Fed. Reg. 37948. According to EPA, these contaminants are known or anticipated to occur in public water systems and may require regulation under the Safe Drinking Water Act (SDWA). The draft list is the Fifth Contaminant Candidate List (CCL 5) published by EPA since the SDWA amendments of 1996. The draft CCL 5 includes 66 chemicals, three chemical groups (PFAS, cyanotoxins, and disinfection byproducts), and 12 microbial contaminants. EPA seeks

comment on the draft CCL 5 and on improvements implemented in the CCL 5 process for consideration in developing future CCLs. Comments are due **September 17, 2021**.

EPA Publishes Interactive Maps And Resources Intended To Empower Public And Policymakers To Act On Environmental Justice: On July 29, 2021, EPA published a new web resource with interactive maps and supporting materials that combine information on air pollution emitted by fossil fuel-fired power plants with key demographical data on nearby communities. According to EPA, the Power Plants and Neighboring Communities initiative advances the Biden-Harris Administration's commitment to environmental justice by empowering the public and policymakers with information and tools to understand better the disproportionate impacts of air pollution in overburdened communities. The mapping tool improves access to data on power plant emissions and can increase understanding of how the power sector affects the air quality and environmental health of surrounding communities. EPA states that by highlighting what groups of people might be impacted and how, the Power Plants and Neighboring Communities web page provides state and local policymakers with information that can be used to protect their most vulnerable populations.

EPA And Army Announce Next Steps For Crafting "Enduring" WOTUS Definition: On July 30, 2021, EPA and the U.S. Department of the Army (Army) announced plans for upcoming community engagements to inform their efforts to revise the definition of "waters of the United States" (WOTUS) to ensure better clean and safe water for all. According to EPA, the agencies intend to revise the WOTUS definition following a process that includes two rulemakings. EPA states that a forthcoming foundational rule would restore the regulations defining WOTUS that were in place until 2015, with updates to be consistent with relevant Supreme Court decisions. A separate, second rulemaking process would refine this regulatory foundation and establish an updated and durable definition of "waters of the United States." EPA and Army announced a series of engagement opportunities, including an opportunity for stakeholders and the public to provide written recommendations and a series of public meetings in **August 2021** to hear perspectives on both rules. 86 Fed. Reg. 41911. Written recommendations are due **September 3, 2021**. In addition, the agencies are initiating federalism and Tribal consultations for the foundational rule. The agencies also intend to host a series of dialogues with state and Tribal co-regulators in **fall 2021** to discuss both rulemakings.

EPA Announces "Clean Trucks Plan": On August 5, 2021, EPA announced its "Clean Trucks Plan." EPA states that to ensure the progress needed on cleaning trucks and buses and to harness improvements in vehicle technologies, EPA will issue two major regulations over the next three years. By **December 2022**, EPA will propose and issue final new stringent emissions standards to reduce nitrogen oxides (NOx) pollution from trucks starting in model year (MY) **2027**. This action will include an update of current greenhouse gas (GHG) standards to capture market shifts to zero-emission technologies in certain segments of the heavy-duty vehicle sector. EPA states that it is also working on new stringent GHG emissions standards for heavy-duty engines and vehicles starting as soon as MY **2030**.

EPA Will Overhaul Pollution Standards For Passenger Vehicles: On August 10, 2021, EPA published a proposed rule that would revise the GHG emissions standards for light-duty vehicles for **2023** and later MYs to make the standards more stringent. 86 Fed. Reg. 43726. EPA proposes to revise the GHG standards to be more stringent than "The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021-2026 Passenger Cars and Light Trucks," standards in each MY from **2023** through **2026**. EPA also proposes to include "several flexibilities to incentivize the production and

sale of vehicles with zero and near-zero emissions technology to reduce compliance costs and to address the lead time of the proposed standards.” In addition, EPA proposes some technical amendments to clarify and streamline the regulations. EPA will hold a public hearing on **August 25, 2021**, on its proposal. 86 Fed. Reg. 43469. EPA will hold an additional session on **August 26, 2021**, if necessary, to accommodate the number of testifiers that sign-up to testify. To register to attend the hearing (to testify or listen-only), e-mail ASD-Registration@epa.gov by **August 18, 2021**.

EPA Releases Ambient Water Quality Criteria To Address Nutrient Pollution In Lakes And Reservoirs: On August 13, 2021, EPA announced the release of *Ambient Water Quality Criteria to Address Nutrient Pollution in Lakes and Reservoirs*. 86 Fed. Reg. 44712. According to EPA, these national recommended criteria are models for total nitrogen and total phosphorus concentrations in lakes and reservoirs to protect three different designated uses -- aquatic life, recreation, and drinking water source protection -- from the adverse effects of nutrient pollution.

EPA Announces Resources Intended To Help Partners Better Address Nutrient Pollution Affecting Waters: EPA released on August 13, 2021, three new resources to assist its state, territorial, and authorized Tribal partners to address adverse effects of nutrient pollution, including freshwater harmful algal blooms (HAB). According to EPA, these resources will help its co-regulators and partners better protect recreators, aquatic life, and drinking water sources from the detrimental effects of nutrient pollution. The three resources include EPA’s Final Recommended Nutrient Criteria for Lakes and Reservoirs; a web-based tool with information and tracking of HABs; and a Technical Support Document to aid implementation of certain HABs criteria.

FDA

Update For FDA’s New Era Of Smarter Food Safety: On July 13, 2021, the U.S. Food and Drug Administration (FDA) released an update for the New Era of Smarter Food Safety Blueprint, released in July 2020, that discusses progress made to date. The FDA Voices post covers Enhanced Food Traceability, Import Screening, Inspections, and other key topics. FDA also released a document titled “New Era of Smarter Food Safety Select Activities for 2021,” which covers planned activities for each priority area of the blueprint.

FDA Guidance For Use Of Recycled Plastics In Food Packaging: On July 16, 2021, FDA released a guidance document titled “Guidance for Industry: Use of Recycled Plastics in Food Packaging (Chemistry Considerations).” This final guidance highlights key chemistry considerations for submitters to consider when evaluating use of recycled plastics in food packaging applications. The guidance addresses possible chemical contaminants, includes testing strategies, and includes a discussion of acceptable effective barriers.

User Fees For FSMA Programs: On July 27, 2021, FDA announced the fiscal year (FY) **2022** user fee rates for the Food Safety Modernization Act (FSMA) Voluntary Qualified Importer Program (VQIP) and the Accredited Third-Party Certification Program (TPP). In addition, on July 28, 2021, FDA announced FY **2022** fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections. 86 Fed. Reg. 40571. These fees are effective **October 1, 2021**, through **September 30, 2022**.

FDA Letter For Fluorinated Food Contact Containers Noting PFAS Concern: On August 5, 2021, FDA issued a letter to manufacturers,

distributors, and users of fluorinated polyethylene food contact articles clarifying that only substances identified and used in accordance with 21 C.F.R. Section 177.1615 are authorized for food contact use. FDA specifically calls attention to the requirement that only gaseous nitrogen may be used as an inert diluent during manufacture, and that the regulation does not authorize use of alternative diluents in the fluorination process (*e.g.*, water, oxygen). The letter mentions that FDA is concerned that fluorinated high-density polyethylene (HDPE) containers possibly containing PFAS may be used in food contact application. The letter encourages manufacturers and distributors to consult with FDA when questions regarding the regulatory status of food contact containers arise.

NANOTECHNOLOGY

Nanomaterials Podcast: In the recent All Things Chemical™ episode Occupational Exposure Limits for Nanomaterials — A Conversation with Carla Hutton, Lynn L. Bergeson and Carla N. Hutton discuss the July 13, 2021, National Institute for Occupational Safety and Health (NIOSH) draft technical report on developing occupational exposure limits or “bands” for engineered nanomaterials, and the issues for which stakeholders may wish to submit comments by the **September 13, 2021** due date.

ISO Publishes Standard Evaluating Methods For Assessing The Release Of Nanomaterials From Commercial, Nanomaterial-Containing Polymer Composites: The International Organization for Standardization (ISO) has published ISO/TR 22293:2021, “Evaluation of methods for assessing the release of nanomaterials from commercial, nanomaterial-containing polymer composites.” The document aims to provide a guide to the information to be taken into account in determining the methods for identifying and evaluating releases of manufactured nanomaterials from matrices; providing a framework for understanding how these methods and the information they produce can support decision-making; and identifying opportunities for developing standards in this area.

ECHA Calls For Tenders To Perform Study On Impact Of Graphene, Graphene Oxide, And Other 2D Materials: The European Chemicals Agency (ECHA) has launched a call for tenders to perform a study “Assessment of the potential impact of graphene, graphene oxide and other 2D materials on health, and the environment” as part of the European Union (EU) Observatory for Nanomaterials (EUON). According to the description, the goal of the study is to conduct a systematic literature review of the health and environmental effects of graphene, graphene oxide, and other two-dimensional (2D) materials, based on existing public information. The deadline for expressing interest was **August 13, 2021**.

EC Committee’s Preliminary Opinion On HAA299 (Nano) As A UV Filter Open For Public Comment: The European Commission’s (EC) Scientific Committee on Consumer Safety (SCCS) has begun a public comment period on its preliminary opinion on HAA299 (nano). The EC asked SCCS whether it considered HAA299 (nano) safe when used as an ultraviolet (UV) filter in cosmetic products up to a maximum concentration of ten percent. According to the preliminary opinion, SCCS considers that HAA299 (nano) as covered within the provided characteristics is safe when used as a UV filter in dermally applied cosmetic products up to a maximum concentration of ten percent. Comments are due **September 27, 2021**. More information is available in our July 27, 2021, blog item.

EUON Publishes Nanopinion On ECHA Nanomaterials Expert Group: On July 15, 2021, EUON published a Nanopinion entitled “The ECHA Nanomaterials Expert Group (NMEG)” by Frank Le Curieux, Scientific Area Leader for Genotoxicity at ECHA. Le Curieux provides a brief summary

of the creation of NMEG and its history. More information is available in our August 2, 2021, [blog item](#).

EC Publishes Report On Use Of Nanomaterials In Cosmetics And Review Of Cosmetics Regulation Regarding Nanomaterials:

Pursuant to Article 16 (10) and (11) of Regulation (EC) No 1223/2009 (Cosmetics Regulation), the EC is required to submit to the European Parliament and the Council an annual status report on the use of nanomaterials in cosmetic products and to review the Regulation's provisions concerning nanomaterials. The July 22, 2021, report includes findings and conclusions. More information is available in our July 28, 2021, [blog item](#).

France Seeks More Protective European Definition Of Nanomaterials:

As reported in our May 7, 2021, [blog item](#), the EC recently held a targeted stakeholder consultation to update, test, and verify the preliminary findings of its review of the 2011 Recommendation on the definition of a nanomaterial. According to a July 23, 2021, [news item](#) posted by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES), in its response to the consultation, ANSES maintained that the changes proposed by the EC "tend to restrict the number and type of objects that will ultimately be considered as nanomaterials." More information is available in our July 29, 2021, [blog item](#).

ACGIH® Will Not Proceed With TLV® For Carbon Nanotubes In

2022: As reported in our January 4, 2021, [blog item](#), the American Conference of Governmental Industrial Hygienists (ACGIH®) Threshold Limit Values for Chemical Substances (TLV®-CS) Committee included carbon nanotubes on its 2021 list of chemical substances and other issues under study. ACGIH® has now released its two-tier under study list. Tier 1 lists the chemical substances and physical agents that may move forward as a notice of intended change (NIC) or notice of intent to establish (NIE) in the upcoming year, based on their status in the development process. Tier 2 consists of those chemical substances and physical agents that will not move forward, but will either remain on or be removed from the under study list for the next year. Carbon nanotubes are included in Tier 2.

EFSA Updates Guidance On Nanomaterials Risk Assessment To Be Applied In Food And Feed Chain: Human And Animal Health:

The European Food Safety Authority (EFSA) has updated its "Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health." The updated guidance, published on August 3, 2021, covers the application areas within EFSA's remit, including novel foods, food contact materials, food and feed additives, and pesticides. The guidance takes into account relevant scientific studies on physico-chemical properties, exposure assessment and hazard characterization of nanomaterials, and areas of applicability. More information is available in our August 6, 2021, [blog item](#).

ISO Publishes Two New Standards For Nanomaterials:

ISO recently published two standards for nanomaterials. ISO/TS 21633:2021, "Label-free impedance technology to assess the toxicity of nanomaterials *in vitro*," describes a methodology of a label-free and real-time detection for non-invasive monitoring of cell-based assays to assess toxicity of nanomaterials to eukaryotic and prokaryotic cells. ISO/TS 23034:2021, "Nanotechnologies --- Method to estimate cellular uptake of carbon nanomaterials using optical absorption," describes a near-infrared optical absorption method to estimate the *in vitro* cellular uptake of carbon nanomaterials, including both internalized and/or tightly adhered to the cell membrane from liquid dispersions.

EFSA Publishes Safety Assessment Of Silver Nanoparticles Intended To Be Used In Plastics: EFSA published a Scientific Opinion entitled “Safety assessment of the substance silver nanoparticles for use in food contact materials.” The abstract states that the additive “is intended to be used as a surface biocide at up to 0.025% w/w in non-polar plastics for contact with a wide variety of foods, times, temperatures and food contact surface/mass of food ratios.” According to the abstract, “[t]he data and information on theoretical considerations, on specific migration and abrasion tests show that, under the intended and tested conditions of uses, the silver nanoparticles stay embedded in the polymer, do not migrate and resist release by abrasion, thus, do not give rise to exposure via food and to toxicological concern.”

BIOBASED/RENEWABLE PRODUCTS

B&C® Biobased And Sustainable Chemicals Blog: For access to a summary of key legislative, regulatory, and business developments in biobased chemicals, biofuels, and industrial biotechnology, go to <http://blog.braginfo.org>.

LEGISLATIVE

House Passes PFAS Action Act: On July 21, 2021, the House passed the PFAS Action Act of 2021 (H.R. 2467). The July 21, 2021, press release issued by the House Committee on Energy and Commerce states that the bill “would protect Americans’ drinking water from toxic PFAS chemicals, which contaminate water and household supplies and poses severe, demonstrated health risks.” The bill “will regulate these toxic ‘forever chemicals,’ clean up contamination, and protect public health.” The House passed the bill by a vote of 241 to 183. The White House issued a Statement of Administration Policy on July 19, 2021, supporting passage of the bill. According to the Statement, “[a]ggressive efforts” to analyze the impact of PFAS on human health and the environment are necessary to meet the challenges associated with developing regulations to reduce exposure to them and improve public health. The Biden-Harris Administration “is pressing forward with targeted actions in its regulatory agenda to achieve this goal, and looks forward to working with the sponsors on this critical issue.”

Senate Committee Passes PFAS Amendment To FY 2022 NDAA Bill: On July 22, 2021, Senator Jeanne Shaheen (D-NH), a member of the Senate Armed Services Committee, announced the adoption of an amendment to the FY 2022 NDAA that would require the investigation and remediation of PFAS at current and former U.S. military installations. According to Shaheen’s press release, the amendment would:

- Codify the PFAS Task Force established by then-Secretary of Defense Mark Esper following his commitment to Shaheen to prioritize combating PFAS;
- Establish a deadline for the Department of Defense (DOD) to test for PFAS at all DOD installations;
- Direct DOD to develop a remediation schedule to address PFAS contamination at military facilities; and
- Require DOD to produce a status report on PFAS remediation efforts at military facilities with some of the highest detections across the country.

The Senate Armed Services Committee passed the amended FY **2022** NDAA, and it will next be considered by the full Senate.

House Bill Would Require FDA To Study And Reassess Chemicals Used In Food: On July 26, 2021, Representative Jan Schakowsky (D-IL), Chair of the House Energy and Commerce Subcommittee on Consumer Protection and Commerce, introduced the Food Chemical Reassessment Act of 2021 (H.R. 4694), which would require FDA to study and reassess chemicals used in food. Representative Rosa DeLauro (D-CT) joined Schakowsky in introducing the legislation. According to Schakowsky's July 26, 2021, press release, "thousands" of chemicals are added to food to make it "last longer, taste better, and look more enticing," but most of these chemicals have entered the food supply through the Generally Recognized As Safe (GRAS) "loophole" and "have not been reevaluated for safety in decades." The bill would:

- Create an Office of Food Safety Reassessment within the Center for Food Safety and Applied Nutrition at FDA to study every three years the safety of at least ten chemicals added to the nation's food, including PFAS, ortho-phthalates, tert-butylhydroquinone, titanium dioxide, potassium bromate, perchlorate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), brominated vegetable oil (BVO), and propyl paraben; and
- Reestablish a food advisory committee to advise the Secretary of Health and Human Services on the standards for reassessment, and the process and methods necessary to complete the work of the office.

More information is available in our August 9, 2021, memorandum.

More Than 130 Lawmakers Urge EPA To Reinstate Waiver For California's Clean Car Standards: On July 27, 2021, the House Committee on Energy and Commerce and the Senate Committee on Environment and Public Works issued press releases announcing that 139 lawmakers wrote to EPA Administrator Michael Regan to urge him to reinstate promptly the Clean Air Act (CAA) waiver for California's Advanced Clean Cars program. According to the press releases, the waiver would restore the authority of California and other states to impose emission standards on light duty vehicles that are more stringent than federal standards and to require automakers to sell zero emission vehicles. The lawmakers made their request in letters that were signed by 113 members of the House of Representatives and 26 Senators.

Safer Beauty Bill Package Would "Protect Consumers From Harmful Products": On July 29, 2021, Representative Jan Schakowsky (D-IL) announced the Safer Beauty Bill Package, which includes four separate bills "that offer a bold and progressive update to an increasingly outdated set of federal cosmetics laws." The Safer Beauty Bill Package includes the following standalone cosmetics bills:

- Toxic-free Beauty Act of 2021;
- Cosmetic Supply Chain Transparency Act of 2021;
- Cosmetic Safety for Communities of Color and Professional Salon Workers Act of 2021; and
- Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2021.

Republican Senators Introduce Legislation To Uphold Navigable Waters Protection Rule: On July 29, 2021, Republicans on the Senate Committee on Environment and Public Works introduced legislation codifying the 2020 Navigable Waters Protection Rule (NWPR). According to the July 29, 2021, press release, “[w]ith the Biden EPA and U.S. Army Corps of Engineers (USACE) promising to replace the NWPR with a new rule that goes even further than the Obama-era WOTUS Rule, this legislation is needed now more than ever.” The press release states that if the NWPR is replaced, EPA “could go as far as to regulate ditches on private lands and converted croplands, which could ultimately inflict severe harm upon the agriculture, construction, home building, forestry, mining, and energy sectors of the economy.” On July 30, 2021, Republican members of the Committee sent a letter to EPA Administrator Michael Regan and Jaime Pinkham, the Acting Assistant Secretary of the Army for Civil Works, seeking additional clarity on the decision to repeal and replace the NWPR.

Appropriations Package Passed By House Includes EPA Funding: On July 29, 2021, the House passed, on a 219 to 208 vote, a package of seven **2022** appropriations bills. The legislation funds the Departments of Agriculture, Education, Energy, Health and Human Services, Housing and Urban Development, Interior, Labor, Transportation, Treasury, and Veterans Affairs, as well as The Judiciary, Army Corps of Engineers, EPA, FDA, Small Business Administration, Social Security Administration, the Executive Office of the President and general government functions of the Executive Branch, military construction activities at DOD, and other independent agencies. According to the July 29, 2021, press release issued by the House Appropriations Committee, the **2022** Interior, Environment, and Related Agencies funding bill includes \$43.4 billion in regular appropriations, an increase of \$7.3 billion -- 20.2 percent -- above 2021. There is also an additional \$2.45 billion of funding for fire suppression. The legislation:

- Creates American jobs through investments in renewable energy development, including offshore wind, and a national initiative to reclaim abandoned mines and cap orphan oil and gas wells;
- Confronts the climate crisis by expanding environmental enforcement efforts, creating a Civilian Climate Corps, and launching a renewed focus on land and water conservation;
- Supports Native American families by investing in a strong and resilient Indian Country, including through education and health care programs;
- Dramatically expands environmental justice efforts to address unacceptable pollution in communities of color; and
- Honors the federal government’s responsibilities to Native Americans.

Food Labeling Modernization Act Of 2021 Introduced In House And Senate: Representatives Frank Pallone, Jr. (D-NJ) and Rosa DeLauro (D-CT) and Senators Richard Blumenthal (D-CT), Sheldon Whitehouse (D-RI), and Ed Markey (D-MA) introduced the Food Labeling Modernization Act of 2021 in their respective chambers. According to an August 4, 2021, House Committee on Energy and Commerce press release, the bill would update front-of-package food labeling requirements, require updates to the ingredient list on packaged foods, and apply consumer friendly labeling requirements.

House Bill Would Protect Firefighters From PFAS: On August 6, 2021, Representatives Debbie Dingell (D-MI) and Brian Fitzpatrick (R-PA) introduced bipartisan legislation to develop educational resources to help protect firefighters, emergency response personnel, and the communities they serve from exposure to PFAS. Senator Gary Peters (D-MI) leads the bipartisan companion bill (S. 231), which the Senate passed at the end of July. According to Dingell's August 6, 2021, press release, the Protecting Firefighters from Adverse Substances (PFAS) Act would direct the U.S. Department of Homeland Security and other federal agencies like EPA, the U.S. Fire Administrations, and the National Institute for Occupational Safety and Health to provide information for federal, state, and local firefighters on training and best practices to reduce, limit, and prevent exposure to PFAS from firefighting foam and turnout gear, as well as resources that identify alternatives for firefighting tools and equipment that do not contain PFAS.

Legislation Introduced To Protect Consumers From Exposure To Phthalates In Food Supply: On August 6, 2021, Senators Dianne Feinstein (D-CA) and Kirsten Gillibrand (D-NY) introduced the Preventing Harmful Exposure to Phthalates Act, a bill to prevent phthalates from contaminating the U.S. food supply. According to Feinstein's press release, phthalates "have been found to leach into food through plastic products and equipment such as tubing, lid gaskets, food preparation gloves, conveyor belts and food packaging materials." The bill would ban phthalates from materials that touch food and ensure that any replacement substance is safe. The bill would also require a review of other products to determine whether they lead to phthalate exposure with consideration of whether communities of color are disproportionately exposed, as well as the health effects of such exposure. The press release states that Representatives Ted Lieu (D-CA) and Katie Porter (D-CA) will be leading companion legislation in the House.

MISCELLANEOUS

CPSC Sues Amazon To Force Recall Of Hazardous Products Sold On Amazon.com: On July 14, 2021, the U.S. Consumer Product Safety Commission (CPSC) announced that it filed an administrative complaint against Amazon.com, "the world's largest retailer, to force Amazon to accept responsibility for recalling potentially hazardous products sold on Amazon.com." CPSC claims that the specified products sold through Amazon's "fulfilled by Amazon" (FBA) program are defective and pose a risk of serious injury or death to consumers and that Amazon is legally responsible to recall them. According to the complaint, the products include "24,000 faulty carbon monoxide detectors that fail to alarm, numerous children's sleepwear garments that are in violation of the flammable fabric safety standard risking burn injuries to children, and nearly 400,000 hair dryers sold without the required immersion protection devices that protect consumers against shock and electrocution." According to the complaint, Amazon acts as a "distributor," as defined by the Consumer Product Safety Act (CPSA), of its FBA products by: (a) receiving delivery of FBA consumer products from a merchant with the intent to distribute the product further; (b) holding, storing, sorting, and preparing for shipment FBA products in its warehouses and fulfillment centers; and (c) distributing FBA consumer products into commerce by delivering FBA products directly to consumers or to common carriers for delivery to consumers. More information is available in our July 21, 2021, blog item.

Maine Will Phase Out Use Of PFAS In Consumer And Industrial Products: On July 15, 2021, "An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution" (LD 1503) was enacted as an emergency measure without the Governor's signature. Under the bill, manufacturers of products for sale in Maine that contain intentionally added PFAS must submit a written notification to the Maine Department of Environmental Protection (MDEP) beginning **January 1, 2023**. Effective

January 1, 2023, the sale of carpets, rugs, and fabrics that contain intentionally added PFAS is prohibited. As of **January 1, 2030**, the sale of any product that contains intentionally added PFAS is prohibited, unless MDEP determines by rule that the use of PFAS in the product is a currently unavoidable use.

APHIS Proposes Exemptions To Regulations Governing Introduction Of Organisms Modified Or Produced Through Genetic Engineering: The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is proposing to exempt plants with additional modifications that could otherwise be achieved through conventional breeding from the regulations that govern the introduction (importation, interstate movement, or release into the environment) of certain organisms modified or produced through genetic engineering. 86 Fed. Reg. 37988. According to APHIS, the exempt plants would have distinct modifications on the paternal and maternal alleles of a single gene resulting from repair of a targeted DNA break; deletions generated using an externally provided repair template; or deletions resulting from repair of two targeted double strand breaks on a chromosome. Comments are due **August 18, 2021**.

EPA Awards More Than \$3 Million Towards Research To Assess Health And Environmental Impacts Of Biotechnology Products: On July 22, 2021, EPA announced that it awarded \$3,041,583 in funding to five institutions to develop science-based approaches to evaluate the potential human health and environmental impacts of new biotechnology products. Each research team is receiving a grant of up to \$760,000 through EPA's STAR Program. According to EPA, their projects will lead to the development of tools and methods that allow decision makers to understand better and monitor how biotechnology products might impact public health and the environment before they are used or released into the environment. The recipients are:

- Georgia Tech, Atlanta, Georgia, to develop a method to track genetically recoded organisms and assess their impacts on natural microbes found in freshwater;
- University of California, San Diego, California, to develop an approach to understand and effectively monitor the dispersal of lab-generated sterile mosquitoes in the Hawaiian Islands;
- University of Colorado, Boulder, Colorado, to create software tools to quantify and predict the effects of synthetic microorganisms on local, native, microbial communities;
- Washington University in St. Louis, Missouri, to develop an auto destruction switch for genetically engineered microorganisms and a system to ensure lab observations can match field predictions; and
- Worcester Polytechnic Institute, Worcester, Massachusetts, to test soils and natural soil microbes for their effects on synthetic microorganisms, and for potential containment functions.

OEHHA Announces Availability Of Draft Technical Support Document And Public Workshop For Proposed Public Health Goals For PFOA And PFOS In Drinking Water: On July 22, 2021, the California Office of Environmental Health Hazard Assessment (OEHHA) announced the release of a draft document for public review describing proposed public health goals (PHG) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water. The draft technical

support document presents the scientific information available on the toxicity of PFOA and PFOS and the calculation of the proposed PHGs. OEHHA will hold a virtual public workshop on **September 28, 2021**. Comments on the draft technical support document are due **September 28, 2021**.

Six Draft ATSDR Toxicological Profiles Available For Public Comment: On July 29, 2021, the Agency for Toxic Substances and Disease Registry (ATSDR) announced the opening of a docket to obtain comments on drafts of six updated Toxicological Profiles: acetone, aldrin/dieldrin, chlorophenols, 3,3-dichlorobenzidine, disulfoton, and pentachlorophenol. 86 Fed. Reg. 40844. ATSDR prepared the drafts of the updated Toxicological Profiles based on the availability of new health effects and other information since their initial release. ATSDR seeks public comments and additional information or reports on studies about the health effects of the six substances for review and potential inclusion in the profiles. ATSDR will evaluate the quality and relevance of such data or studies for possible inclusion in the profile. Comments are due **October 27, 2021**.

ATSDR Requests Nominations For Proposed Substances To Be Evaluated For Toxicological Profile Development: ATSDR requests public nominations of substances for ATSDR to evaluate for Toxicological Profile development. 86 Fed. Reg. 40843. ATSDR will consider nominations from the Substance Priority List (SPL). ATSDR will also accept nominations for substances not on the SPL that may have public health implications, on the basis of ATSDR's authority to prepare Toxicological Profiles for substances not found at sites on the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) National Priorities List. Nominations are due **August 30, 2021**.

EPA Announces Selections Of SAB Charter Members And SAB Standing Committee Members: On August 2, 2021, EPA Administrator Michael S. Regan announced his selections for membership of the Science Advisory Board (SAB), which will be comprised of 22 women and 25 men, including 16 people of color, "making it the most diverse SAB since the committee was established." According to the press release, Regan's selections "are well-qualified experts with a cross-section of scientific disciplines and experience needed to provide advice to EPA leadership to help advance the agency's mission." The selections include six prior members of the 2020 Chartered SAB and a total of 19 members who have served on prior Chartered SABs and SAB Standing Committees.

President Signs Executive Order Outlining Target Of 50% Electric Vehicle Sales Share In 2030: On August 5, 2021, President Joseph Biden signed an Executive Order that sets a new target to make half of all new vehicles sold in **2030** zero-emissions vehicles, including battery electric, plug-in hybrid electric, or fuel cell electric vehicles. 86 Fed. Reg. 43583. According to the White House fact sheet, the Executive Order "also kicks off development of long-term fuel efficiency and emissions standards to save consumers money, cut pollution, boost public health, advance environmental justice, and tackle the climate crisis."

EPA Announces 11th Annual Tribal Lands And Environment Forum: On August 10, 2021, EPA announced that the upcoming 2021 Tribal Lands and Environment Forum (TLEF): A Virtual Gathering will be held **August 16-19, 2021**. According to EPA, this year's interactive sessions will engage and train EPA's Tribal partners, as well as other stakeholders, including federal, state, and local governments, academia, non-profit organizations, consultants, students, and others, on effectively implementing EPA's brownfields, emergency response, solid and hazardous waste,

Superfund, underground storage tanks, and other program areas in Indian country. Registration is free.

This Update is provided as a complimentary service to our clients and is for informational purposes. This Update may be copied or quoted, provided proper attribution is given. The contents are not intended and cannot be considered as legal advice.

ABOUT THE FIRM

B&C® helps companies making and using chemicals commercialize their products, maintain compliance, and achieve competitive advantage as they market their products around the world. We provide powerful solutions for regulatory, political, and scientific challenges in any jurisdiction.

BERGESON & CAMPBELL, P.C.
2200 Pennsylvania Ave., N.W.
Suite 100W
Washington, D.C. 20037
(202) 557-3800
(202) 557-3836 (fax)
www.lawbc.com